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# Comparison of the Teno Fix Tendon Repair System and a standard suture repair in Zone II flexor tendon lacerations of the hand.

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 30/09/2005 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/09/2005 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 26/04/2011 | Injury, Occupational Diseases, Poisoning | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
N0013145917

## Study information

### Scientific Title

### Study objectives
Is there a reduced rupture rate and improved outcome using the Teno Fix Tendon Repair System in comparison to a standard suture repair in zone II flexor tendon lacerations in the hand?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Study type(s)
Not Specified

### Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Tendon lacerations

### Interventions
Randomisation of adult patients with zone II flexor tendon lacerations to receive either the Teno Fix repair or standard suture repair. Assessment of outcomes by blinded, independent observer.

Added 29 July 2008: trial stopped in 2006 due to poor recruitment.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Tendon rupture rate and digital range of motion at 12 weeks post-repair.

### Key secondary outcome(s))
Not provided at time of registration

### Completion date
01/09/2003

### Reason abandoned (if study stopped)
Poor recruitment

## Eligibility

### Key inclusion criteria
Adult patients with acute Zone II flexor tendon lacerations in the hand.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Not Specified

### Key exclusion criteria
1. Adults above 60 yrs of age
2. Flexor tendon lacerations outside Zone 2
3. Complex injuries, eg crush, mutilation, skin loss, amputations, revascularisation
4. The presence of established infection in injured hand
5. Associated digital fractures
6. Delayed surgery
7. Severe intercurrent medical illness
8. Drugs, eg immunosuppressives, steroids, which can affect healing
9. Previous injuries to affected hand
10. Pre-existing arthritis in affected hand
11. Allergy to metals in the stainless steel suture of Teno Fix (chromium, copper, cobalt, nickel, iron)

### Date of first enrolment
01/03/2003

### Date of final enrolment
01/09/2003

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Plastic Surgery**
London
United Kingdom
SE1 7EH

# Sponsor information

**Organisation**
Department of Health

# Funder(s)

**Funder type**
Government

**Funder Name**
Guy's and St. Thomas' NHS Foundation Trust (UK) Own account

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration